

REMARKS

Entry of the foregoing, reexamination and reconsideration of the above-identified application are respectfully requested.

The Official Action notes that the application does not contain a required Abstract. An Abstract is submitted herewith.

Applicants note with appreciation the indication that claims 23, 26 and 27 are objected to as depending from a rejected base claim. In view of the above amendments, it is believed that all of the claims are in condition for allowance.

Claims 1 and 22 have been amended to more clearly define the conversion reagent. More specifically, the recitations of claims 17 and 18 were incorporated into claim 1 as well as into claim 22. Claim 6 was amended to define "at least 50%w/w" of the α -lactalbumin as being in the molten globule-like state. Support for this amendment may be found at the very least at page 4, lines 26-30. Claims 10 and 11 were amended to define the pH as being a pH of 2. Support for this amendment may be found at the very least at page 6, lines 7-10. Claim 16 was amended to recite the full name for "EDTA" and claim 36 was amended to define "DEAE." These abbreviations were well recognized in the art at the time the application was originally filed. The specification has also been amended to incorporate the full names for these well recognized chemicals. Claim 34 was amended to define the elevated temperature as being between 25-120°C, which amendment finds support at the very least at page 6, lines 10-13.

New claims 47-49 were added to the instant application. Support for these claims may be found at the very least at page 9, line 33 to page 10, line 4.

No new matter is added by any of the instant amendments.

Claims 1-46 were rejected under 35 U.S.C. §112, second paragraph, as allegedly failing to define the invention. This rejection is respectfully traversed.

It is respectfully believed that this rejection is overcome by the instant amendments to the claims. The recitation of "at least some" has been deleted from the claims. "Substantial portion" has been deleted from claim 6. In addition, "conversion agent" has been defined in claim 1. "Low pH" has been amended to instead recite pH of 2. Claim 12 has been amended to recite 25°C-120°C. Claims 14 and 15 have been amended to define the "reagent" as being a "molten globule inducing" reagent. Claim 16 has been amended to recite the chemical name for EDTA, and claim 36 similarly amended for DEAE. Claims 17 and 18 have been deleted. Claim 19 has been amended to depend from claim 1. Claim 20 has been amended to define how the α -lactalbumin has been modified. Claim 21 has been amended to delete the recitation of "at least some." Claim 24 has been amended to delete "substantially." Claim 33 has been amended to recite "pH of 2" rather than "low pH." Claim 34 has been amended to define the heating temperature range. Claims 41 and 42 have been amended to correct the noted informalities. Claim 45 has been amended to be more clear.

In view of the instant amendments, it is respectfully believed that the rejection under §112(2) has been overcome. Withdrawal of the rejection is respectfully requested and believed to be in order.

Claims 1, 2, 6 and 28 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Jegouic et al. This rejection is respectfully traversed.

Jegouic et al is cited as teaching "baric oligomerization of alpha-lactalbumin that is treated with low-molecular weight reducing thiols (conversion reagents) see page 19, lines 1-5 of the introduction." Official Action, page 5. The treatment allegedly "partially unfolds the proteins and converts them into a molten globule-like state (reduction of the disulfide bonds, page 5 of the specification), Official Action, page 5. Jegouic et al, however, fails to disclose or even suggest the instantly claimed invention.

Claims 1, 2, 6 and 28 are not disclosed or suggested by Jegouic et al. These claims all require that the α -lactalbumin be in the molten globule-like state and require the use of a “conversion reagent selected from the group consisting of fatty acids and lipids, wherein said fatty acids and lipids are found in a casein containing fraction obtainable from human milk.” Jegouic et al fails to teach or suggest the use of such a conversion reagent. While the low molecular weight reducing thiols discussed therein can be “conversion reagents,” they do not fall within the scope of the claimed invention since they cannot be obtained from human milk. Jegouic et al thus fails to disclose or suggest the instant invention.

In view of the above, withdrawal of the rejection of record is respectfully requested and believed to be in order.

Claims 1-3, 6, 14, 17, 18, 22, 25, 28, 35-42 and 46 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Jegouic et al in view of Sabharwal and Ohgushi et al. This rejection is respectfully traversed.

Jegouic et al is an academic study illustrating how oligomeric forms of α -lactalbumin may be prepared. Significantly, however, the present invention is not concerned with just any oligomeric form of α -lactalbumin. Instead, it relates to the preparation of a particular form which has a specific biological activity, as defined on page 4, lines 1-3 of the specification.

As stated *supra*, Jegouic et al (the primary reference) fails to teach the use of a “conversion reagent selected from the group consisting of fatty acids and lipids, wherein said fatty acids and lipids are found in a casein containing fraction obtainable from human milk.” Since a different conversion reagent is employed, the resulting products may differ. There is absolutely no evidence that the oligomeric form of Jegouic et al has the same activity as the instant invention.. It should be noted that applicants have found that the preparation conditions, and in particular the presence of the fatty acid, such as oleic acid, is extremely

important in obtaining and stabilizing this particular form. As a result, it should not be assumed that the oligomers of Jegouic et al would have this same activity.

Sabharwal teaches that the biologically active form can be prepared from human milk by separation in a particular way, using an ion exchange column. It does not explain how this occurs. It is silent, for example, on whether the α -lactalbumin is in the molten globule state or not, and on the need for any conversion reagents or cofactors. Therefore, it would not be obvious from this reference to produce a biologically active form of α -lactalbumin using a conversion reagent as claimed. The conversion agents are neither disclosed nor suggested. Nor does Sabharwal teach that the molten globule state is required.

Ohgushi fails to overcome or remedy the deficiencies of Jegouic et al and Ohgushi. Ogushi broadly describes molten globule states of proteins. It speculates, on page 24, that they may play a role in biochemical functions. However, this is a sweeping generalization. It is not specific to α -lactalbumin in any way. Nor is it specific in terms of biological activity of the molten globule states of proteins and how the activity would be affected. A skilled person reading this reference would not with any reasonable degree of certainty, assume that the biological activity of Sabharwal was a result of the molten globule state of the protein, or that the properties of α -lactalbumin could be affected by converting the protein to the molten globule-like state

Moreover, the unexpected results of the instant invention are neither disclosed nor suggested by the cited art. Applicants have found that contact with a *particular type* of conversion reagent has been found to be essential to the production of the biologically active form of α -lactalbumin, as defined in the instant application and the claims. This particular type of reagent, as defined in the claims, is neither disclosed nor suggested by the cited art. It would not be clear from any of the prior art that a fatty acid, such as oleic acid, which is found in the casein containing fraction of human milk, is required as a conversion reagent.

Hence, it would not be obvious from these references that one could obtain a biologically active oligomeric complex using just α -lactalbumin and specifically a lipid or fatty acid found in human milk. Jegouic et al does not suggest that fatty acids would act as "conversion reagents." Nor does Ohgushi suggest this, although it is concerned with the formation of molten globule states. Sabharwal is silent on the need for the α -lactalbumin to go through the molten globule state, and furthermore, gives no indication that the fatty acid or lipid present in human milk is a specifically required conversion reagent. The conversion agent of Jegouic et al would not produce the oligomeric form which had the biological activity which is a feature of the present invention. The combination of references thus would not disclose or suggest the claimed invention.

In view of the above, the claims now pending are neither disclosed nor suggested by the Patent Office. The cited art does not render obvious the claims of record. Withdrawal of the rejection of record is respectfully requested and believed to be in order.


It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, further and favorable action in the form of a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (650) 622-2360 so that prosecution of the application may be expedited.

Respectfully submitted,

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